REMARKS

In reply to the Office Action of February 22, 2006, Applicants have amended claims 2 and 5. Claims 2, 3, 5, 12, 14 to 22 and 42 are pending and under examination. No new matter is added by this amendment.

Claim 5 was objected to for referring to "cefozoprane" instead of "cefozopran." Claim 5 was amended to refer to "cefozopran," therefore the objection should be withdrawn.

The specification was also objected to for using the term "cefozoprane" instead of "cefozopran." Appropriate correction has been made to the specification, rendering the ojecton moot.

Obviousness-type double patenting

Claims 2, 3, 5, 12, and 14-22 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 8-11, 14-21, 24, 31, and 32-34 of U.S. Patent No. 6,248,360. The claims of the present application are directed to a pharmaceutical composition that includes four elements, namely, (1) a biopolymer; (2) an antimicrobial agent consisting of a cephalosporin, wherein the antimicrobial agent is entrained within or ionically bound to the biopolymer; (3) a metal cation entrained within or ionically bound to the biopolymer or the cephalosporin; and (4) an absorption enhancer. The Office Action Mailed March 14, 2003 recognizes that "the '360 patent does not claim a pharmaceutical composition that comprises an adsorption [sic] enhancer." In support of the double patenting rejection, the Examiner relied upon examples in the '360 patent to supply an adsorption enhancer, which was disclosed, but not claimed.

With the recognition of Applicant's priority claim, the '360 patent is not prior art, and therefore the disclosure of the '360 patent cannot be properly relied upon in support of a rejection under 35 U.S.C. 103(a). Unlike a rejection under 35 U.S.C. 103(a), "the law of double patenting is concerned *only* with what patents *claim*. "Double patenting," therefore, involves an inquiry into what, if anything, has been claimed twice." (See *General Foods Corp. v. Studeingesellschaft Kohle mbH*, 23 USPQ2d 1839, 1841 (Fed. Cir. 1992).

The Examiner asserts that portions of the specification which provide support for the patent claims may also be examined when considering issues of double patenting. However, the portions of the specification relied upon by the Examiner do not provide support for any of the patent claims in the '360 patent. Specifically, although the examiner relies on examples in the specification of an adsorption enhancer, these examples do not support a claim in the '360 patent that recites an adsorption enhancer.

Because the analysis of double patenting is limited to a determination of whether something has been improperly claimed twice, the analysis is properly limited to the claims and portions of the specification supporting those claims. The Examiner's reliance on examples that do not support the claims that provide the basis for the double patenting rejection is improper. Therefore the rejection should be withdrawn.

Rejection under 35 U.S.C. 103(a)

Claims 2, 3, 5, 12, and 14-22 were rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,458,287 to Scott et al., in view of WO 98/30207 to Watts et al. The pending claims recite a pharmaceutical composition for oral delivery of a cephalosporin. The composition includes a biopolymer, an antimicrobial agent consisting of a cephalosporin, wherein the antimicrobial agent is entrained within or ionically bound to the biopolymer, a metal cation entrained within or ionically bound to the biopolymer or the cephalosporin, and an absorption enhancer.

Scott discloses methods and compositions for forming sustained release microspheres. (Scott, col. 1, lines 3-4.) "The microspheres of the invention include a macromolecule, preferably a protein or a nucleic acid, and at least one water soluble polymer. " (Id. col. 3, lines 28-30.) Specifically, Scott describes a macromolecule as follows:

> The macromolecule forming the microsphere is any molecule having a tertiary and quaternary structure or capable of having a tertiary and quaternary structure. Most preferably, the macromolecule is a biomolecule such as a protein, including enzymes and recombinant proteins, a peptide, carbohydrate, polysaccharide, carbohydrate- or polysaccharide-protein conjugate, nucleic acid, virus, virus particle, conjugate of a small molecule (such as a hapten) and protein, or mixtures thereof. An organic or inorganic natural or synthetic pharmaceutical compound or drug may be incorporated into the microspheres by attaching the drug to

> a macromolecule, such as a protein, and then forming the microspheres from the macromolecule-drug complex or conjugate. (Id. Col 12, lines 22-35.) Emphasis added.

The compositions disclosed in Scott require a macromolecule that has or is capable of having tertiary and quaternary structure. Compounds lacking such structure, like a drug or other pharmaceutical, are only incorporated into the microsphere by attachment to a macromolecule. Thus, Scott requires that when compounds such as cephalosporins, which lack tertiary or quaternary structure, are used, the active agent is that compound in conjunction with a macromolecule to provide an agent with the required structure.

The pending claims recite a composition consisting of an antimicrobial agent, wherein the antimicrobial agent is ionnically bound to a biopolymer. The antimicrobial agent recited in the claims, like the drug and pharmaceutical agents disclosed in Scott, lacks the tertiary and quaternary structure necessary to be incorporated in the microspheres of Scott. Moreover, the closed language, consisting of, precludes compositions disclosed by Scott, i.e., an active agent having tertiary or quaternary structure based on the combination of an antimicrobial and a macromolecule. Therefore Scott does not disclose or suggest an antimicrobial agent ionnically bound to a biopolymer as required by the claims.

Watts describes, *inter alia*, drug compositions comprising chitosan, type A cationic gelatin, and a therapeutic agent. However, Watts fails to remedy the defects of Scott because Watts fails to disclose an antimicrobial agent as required by the claims. Because Scott and Watts, both alone and in combination, fail to disclose or suggest every element in the pending claims, a *prima facie* case of obviousness cannot be maintained. Applicants therefore request that the rejection be withdrawn.

Claims 2, 3, 5, 12, 14-22, and 42 are rejected under 35 U.S.C. 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,458,287 to Scott et al., in view of WO 98/30207 to Watts et al, in further view of U.S. Patent No. 5,783,561 to Horwitz et al. The combination of Scott and Watts fail to support a *prima facie* case of obviousness for at least the reasons above. Horwitz does not provide the teaching missing from the combination of Scott and Watts, namely that of an antimicrobial agent as currently claimed, nor is Horwitz relied upon for such a teaching.

Therefore, the combination of Scott, Watts and Horwitz does not support a *prima facie* case of obviousness and the rejection should be withdrawn.

The fees in the amount of $1020 are being paid concurrently herewith for the Petition for Extension of Time on the Electronic Filing System (EFS) by way of Deposit Account authorization. Please apply any other charges or credits to deposit account 06-1050, referencing attorney docket number 19916-003001.

Respectfully submitted,

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